EXHIBIT A

FDA U.S. FOOD & DRUG ADMINISTRATION

Premarket Approval (PMA)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	NUCLEUS COCHLEAR IMPLANT SYSTEM
Generic Name	Implant, Cochlear
Applicant	Cochlear Americas 13059 East Peakview Avenue Centennial, CO 80111
PMA Number	P970051
Supplement Number	S137
Date Received	11/23/2015
Decision Date	07/08/2016
Product Code	MCM[24]
Advisory Committee	Ear Nose & Throat
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval requested for 1) a change in indications to allow MRI of implant recipients at 1.5T with the implant magnet in place for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST) provided that a Cochlear-supplied MRI kit is used; 2) a change in indications to allow MRI of implant recipients at 3.0T with the implant magnet removed for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST); and 3) consolidation of MRI-related labeling into a single document that provides appropriate instructions for the following Cochlear-manufactured implants: CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), CI24RE(ST), CI24R(CA), CI24R(CS), CI24R(ST), CI24M, and CI 11+11+2M.

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